

Application No.: 10/830071
Filing Date: April 23, 2004

REMARKS

Claims 18, 35 and 44 are amended to recite an identifying step. Support for this amendment can be found, for example, at page 5, first paragraph. New claim 53 is added. Support for this claim can be found, for example, in Example 1 of the specification.

35 U.S.C. § 102(e) - Anticipation

The Examiner has rejected claims 18-26 and 35-52 under 35 U.S.C. § 102(e) as being anticipated by Jennings (U.S. Publication No. 2004/0029941) for the reasons of record. The Jennings Application was filed May 2, 2003, and claims priority to Provisional Application Serial No. 60/378,446, filed May 6, 2002. Thus, without conceding the appropriateness of the priority claim, the earliest effective filing date of the Jennings Application is May 6, 2002.

Applicants submit herewith a Declaration under 37 C.F.R. § 1.132. The Declaration demonstrates that to the extent that the Jennings Application discloses the claimed invention, the Jennings Application is a description of Applicants' own work, and thus, Jennings is not available as prior art under 35 U.S.C. § 102(e).

M.P.E.P. § 2136.05 states:

When a prior U.S. patent, U.S. patent application publication, or international application publication is not a statutory bar, a 35 U.S.C. 102(e) rejection can be overcome ... by submitting an affidavit or declaration under 37 CFR 1.132 establishing that the relevant disclosure is applicant's own work. *In re Mathews*, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969). *M.P.E.P. § 2136.05* (emphasis added).

Declaration pursuant to 37 C.F.R. § 1.132

In order to overcome a 35 U.S.C. § 102(e) reference with a declaration pursuant to 37 C.F.R. § 1.132, the M.P.E.P. states that the following must be shown in the declaration:

When the reference reflects applicant's own work, applicant need not prove diligence or reduction to practice to establish that he or she invented the subject matter disclosed in the reference. A showing that the reference disclosure arose from applicant's work coupled with a showing of conception by the applicant before the filing date of the reference will overcome the 35 U.S.C. 102(e) rejection. The showing can be made by submission of an affidavit by the inventor under 37 CFR 1.132. *M.P.E.P. § 2136.05* (emphasis added).

Thus, according to the M.P.E.P., a declaration under 37 C.F.R. § 1.132 needs to show: 1.) conception prior to the filing of the cited reference; and 2.) that the disclosure of the cited reference arose from applicant's work. Applicants' Declaration pursuant to 37 C.F.R. § 1.132 demonstrates that Applicants conceived of the claimed invention before the filing date of the Jennings reference, and that the portion of the Jennings reference cited against Applicants arose from Applicants' work.

Conception

The Declaration and accompanying Exhibits show that Applicants conceived of the use of zonisamide as a weight loss agent, and proposed a clinical trial to demonstrate zonisamide's efficacy. The clinical trial proposals submitted with the Declaration are dated September 7, 2000, and October 11, 2000. This demonstrates conception of the claimed invention by Applicants prior to the earliest available filing date for the Jennings Application, May 6, 2002.

Applicants' Own Work

The Declaration shows that copies of the proposals for the zonisamide clinical trial were provided to Elan, the original assignee of the Jennings Application, and Julianne Jennings' employer. The Declaration shows that Dr. Gadde prepared an abstract describing the initial results of the zonisamide study performed at the direction of Applicants, a copy of which was provided to Elan prior to the earliest filing date of the Jennings Application. A comparison of the Jennings Application to the clinical trial proposals and Duke Study Abstract submitted with the Declaration show that the study and results described in the single Example in the Jennings Application arose from Applicants' work.

For example, the Jennings Application states under the heading "Objective" that "Short-term efficacy and safety of zonisamide in the treatment of obesity was evaluated," (*Jennings* at ¶ [0039]), while the Duke Study Abstract states under the heading "Objective" that "we evaluated [zonisamide's] short-term efficacy and safety in the treatment of obesity."

Under the heading "Study Population," the Jennings Application lists 3 "Inclusion Criteria" and 17 "Exclusion Criteria." *Jennings* at ¶¶ [0040]-[0062]. These are essentially identical to the inclusion and exclusion criteria found in Applicants' clinical trial proposal.

Paragraph [0063] of the Jennings Application describes the "Method" of the study. This is essentially identical to the "Method" section of the Duke Study Abstract.

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The “Study Drug and Dosing” section of the Jennings Application (§§ [0065]-[0070]) is essentially identical to the same portion of Applicants’ clinical trial proposal, with a minor typographical difference (“100 mg/d” versus “100 mg qd”).

Finally, and most significantly, the “Results” and “Conclusion” sections of the Jennings Application (§§ [0071]-[0072]) are essentially identical to the “Results” and “Conclusion” sections of the Duke Study Abstract.

In addition, Applicants note that the first portion of paragraph [0003] of the Jennings Application is nearly identical to the “Rationale” section of Applicants’ clinical trial proposal.

Conclusion

The Declaration demonstrates that the disclosure of the cited Jennings reference arose from Applicant’s work. Combined with Applicants’ demonstration of conception prior to the earliest available filing date of the Jennings Application, Applicants have made a sufficient showing under 37 C.F.R. § 1.132 to overcome the Jennings Application as 35 U.S.C. § 102(e) art. For at least this reason, Applicants request that the Examiner withdraw the rejection of the pending claims over Jennings.

Provisional Non-statutory Obviousness-type Double Patenting Rejections

The Examiner has rejected the pending claims over three pending applications: U.S. Application Serial Nos.: 11/058,981, 11/059,027, and 11/034,316.

Applicants note that the 11/034,316 application is later-filed than the instant application, with a filing date of January 11, 2005, and an earliest priority date of January 13, 2004. The instant application was filed April 23, 2004, and claims priority to May 17, 2002. The M.P.E.P. states that:

If a “provisional” non-statutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. *M.P.E.P. § 804 I.B(1)* (emphasis added).

In addition, Applicants note that the 11/058,981 and 11/059,027 applications have an actual filing date that is later than the instant application, February 15, 2005, although they share the same priority date as the instant application. As stated above, according to the M.P.E.P.:

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If “provisional” ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application ... If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

Without conceding the propriety of the rejection of the pending claims over the claims of the 11/058,981 and 11/059,027 applications, Applicants note that the claims of the instant application can be considered claims to the “base invention” because the independent claims pending in the 11/058,981 and 11/059,027 applications require two active pharmaceutical compounds while the independent claims of the instant application require only one. Thus, the Examiner should withdraw the provisional ODP rejection in the current application.

In view of the above, Applicants respectfully request that the Examiner withdraw the provisional non-statutory obviousness-type double patenting rejection of the pending claims over the claims of the 11/058,981, 11/059,027, and 11/034,316 applications, and allow the instant application to issue.

Non-Provisional Non-statutory Obviousness-type Double Patenting Rejections

Claims 18-26 and 35-52 are rejected on the grounds of non-statutory obviousness-type double patenting over claims 1-11 of U.S. Patent No. 7,109,198.

In the interest of advancing prosecution, Applicants provide herewith a terminal disclaimer to obviate this rejection. A terminal disclaimer submitted in this application is not an admission of the propriety of the rejection. *See* M.P.E.P. § 804.02; *see also Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991) (noting that “the filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection.”). In view of the terminal disclaimer, Applicants respectfully request withdrawal of the non-provisional non-statutory obviousness-type double patenting rejection of the pending claims over U.S. Patent No. 7,109,198.

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No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Patents and Applications of Assignee

Applicants wish to draw the Examiner's attention to the following patents and applications of the present application's assignee. Applicants encourage the Examiner to monitor the course of prosecution of the following patent applications throughout the pendency of this application.

Patent / Serial Number	Title	Issued / Filed
7,109,198	METHOD FOR TREATING OBESITY	9/19/2006
11/058,981	METHOD FOR TREATING OBESITY	2/15/2005
11/059,021	METHOD FOR TREATING OBESITY	2/15/2005
11/059,027	METHOD FOR TREATING OBESITY	2/15/2005
11/222,135	METHOD FOR TREATING OBESITY	9/7/2005

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CONCLUSION

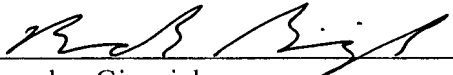
In view of the above, Applicants respectfully maintain that claims are patentable and request that they be passed to issue. Applicants invite the Examiner to call the undersigned if any remaining issues may be resolved by telephone.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 11/16/07

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